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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,182	02/12/2001	John N. Vournakis	7867-022-999	2779
20583	7590	01/24/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			LEWIS, PATRICK T	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 01/24/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/781,182

Applicant(s)

VOURNAKIS ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-66 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 39-66 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 12 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Response Dated October 6, 2004

1. In the Response filed October 6, 2004, claims 39, 44, 50, 51, and 59 were amended. Claims 39-66 are pending. An action on the merits of claims 39-66 is contained herein below.
2. The rejection of claims 39-66 under 35 U.S.C. 112, second paragraph, is maintained for the reasons of record set forth in the Office Action dated April 6, 2004.
3. The rejection of claims 39-66 under 35 U.S.C. 103(a) is maintained for the reasons of record set forth in the Office Action dated April 6, 2004.

Rejections of Record Set Forth in the Office Action Dated April 6, 2004

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 39-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed October 6, 2004 have been fully considered but they are not persuasive. Applicant argues:

"In light of the instant specification, Applicants submit that those of skill in the art would appreciate that 'non-barrier forming' materials, as recited in the instant claims, are porous materials that do not 'provide a mechanical matrix that adheres to the site of application and seals the boundaries' of a wound (page 12, lines 11-13 of the specification as filed). Moreover, the skilled worker would understand that, in this context, such porous, non-barrier forming materials could

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be formulated, e.g., as porous gels, sponges, films, or membranes, or could be formulated as foams, sprays, emulsions, suspensions, or solutions, that comprise the recited poly- β -1 \rightarrow 4 N-acetylglucosamine polymers.”

The examiner disagrees with applicant's position. The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. The USPTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say. While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. In the instant case, applicant has failed to particularly point out the boundaries of what constitutes “non-barrier forming” materials.

Applicant directs the examiners attention to a citation on the page 12 of the instant specification for support of the definiteness of the term. The passage reads, “That is, according to the present invention, the material need not be a barrier-forming

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material that provides a mechanical matrix that adheres to the site of application and seals the boundaries of the wound.” The cited passage fails to give a clear definition of the term “non-barrier forming” and what is encompassed by the term “non-barrier forming material”. The passage simply states that the formation of a barrier is not required in practicing the instant method. The ordinary and customary meaning of the term “barrier” is 1) something that hinders or restricts or 2) a boundary : limit. When the N-acetylglucosamine composition of the instant method is applied topically as a gel, sponge, film, or membrane, as required in instant dependent claim 50, a “barrier” or “boundary” between the treatment site and the environment outside the treatment site is inherently created. Gels, sponges, films, and membranes would be considered “barriers” to one of ordinary skill in the art. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term.

6. Claims 39-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vournakis et al. US 5,635,493 (Vournakis) in view of Barton et al. *Curr. Opin. Nephrol. Hypertens.* (1999), Vol. 8, pages 549-556 (Barton) and Pearson *Lupus* (2000), Vol. 9, pages 183-188 (Pearson).

Applicant's arguments filed October 6, 2004 have been fully considered but they are not persuasive. Applicant argues that Vournakis does not teach or suggest the use of porous non-barrier-forming materials comprising p-GlcNAc to induce transient,

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localized physiological responses and/or a transient, localized modulation of vascular structure and/or function. Moreover, the combination of references cited fail to render obvious the dependent claims that recite methods resulting in stimulation of endothelin-1 release. Additionally, applicant argues the examiner has failed to provide motivation and one of ordinary skill in the art would not have a reasonable expectation of success.

The examiner disagrees with applicant's characterization of the prior art. Vournakis teaches methods and compositions comprising p-GlcNAc materials (column 36, lines 45-52). The materials may be used to promote hemostasis and wound healing (column 35, lines 40-52). The p-GlcNAc materials are applied directly to bleeding surfaces thereby arresting bleeding by providing a mechanical matrix that promotes clotting (column 35, lines 46-48). The p-GlcNAc material of Vournakis is within the MW range of the p-GlcNAc material of the instantly claimed method. Vournakis teaches each of the methodological steps employed in the instantly claimed method. Vournakis is silent on whether the application of the instantly claimed compositions causes endothelin-1 release or vasoconstriction. It would have been obvious to one of ordinary skill in the art at the time of the invention that the method described by Vournakis would also induce the release of endothelin-1 and vasoconstriction since Vournakis teaches that the GlcNAc materials are used to promote hemostasis and wound healing, and Pearson teaches that normal endothelial cell function is critical for all aspects of vascular homeostasis. Pearson further teaches that the active metabolism of these cells is necessary for the continuous adjustment of vascular tone, and hence, the control of blood pressure; for the physiological regulation

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of leukocyte traffic from blood tissues; and for the maintenance of an antithrombotic and anticoagulant balance in flowing blood (page 183, column 1).

The links between hemostasis, wound healing, endothelin-1, and vasoconstriction were known at the time of the invention; however, the recognition of this relationship is not necessary in determining patentability in the instant case since artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. In construing process claims and references, it is the identity of manipulative operations which leads to finding of unpatentability. In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Vournakis teaches topically administering to a patient in need thereof, a material comprising p-GlcNAc within the prescribed molecular weight limitations of the instant claims. Vournakis teaches that the compositions are formulated into membranes, sponges, or gels (column 24, lines 36-44). The p-GlcNAc formulations taught by Vournakis meet the limitations of molecular weight and physical form recited in the instant claims. The response (achievement of at least a transient, localized, modulation of vascular structure and/or function) is not an active methodological step in the process but is rather a consequence of the physiological response of the treated tissue to the p-GlcNAc material. Prima facie obviousness is not rebutted by merely recognizing additional advantages or latent properties in the prior art.

Regarding applicant's arguments regarding motivation and expectation of success, Vournakis explicitly teaches performing the instantly required methodological

steps. One of ordinary skill in the art would have motivated to perform the steps of the method of Vournakis to treat wounds or reduce wrinkles since such a method is set forth in the prior art. The skilled artisan would have had a reasonable expectation of success since Vournakis explicitly teaches the use of the p-GlcNAc material to treat wounds and reduce wrinkles.

Applicant's arguments directed to the use of "porous" materials have been noted; however, the sponges taught by Vournakis meet this limitation.

Conclusion

7. Claims 39-66 are pending. Claims 39-66 are rejected. No claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

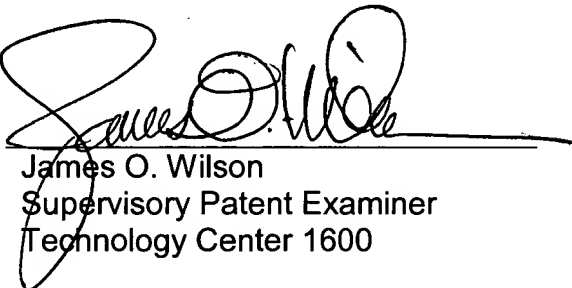
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



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